Human Research Program Informed Consent Briefing

Alan Moore, Ph.D.

Evaluation of Maximal Oxygen Uptake (VO₂max) and Submaximal Estimates of VO₂max Before, During and After Long Duration ISS Missions

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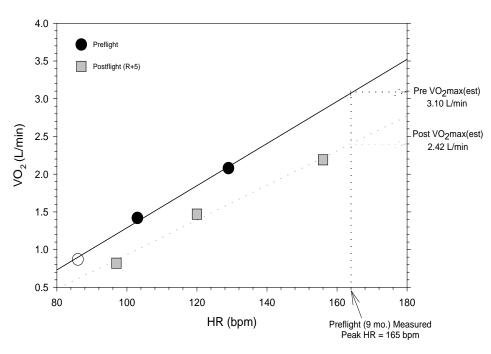
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Background

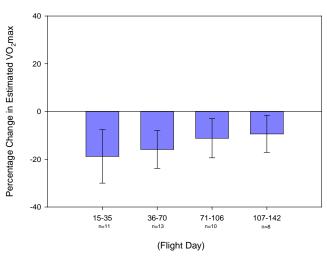
- NASA's Human Research Program Integrated Research Plan (HRP-47065) serves as a road-map identifying critically needed information for future space flight operations (Lunar, Martian)
- ➤ VO₂max (often termed "aerobic capacity") reflects the maximum rate at which oxygen can be taken up and utilized by the body during exercise
- Lack of in-flight and immediate postflight VO₂max measurements was one area identified as a concern
- ➤ The risk associated with not knowing this information is: "Unnecessary Operational Limitations due to Inaccurate Assessment of Cardiovascular Performance" (HRP-47065)

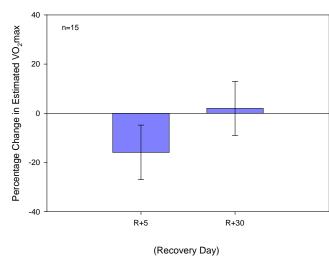
Background



- Currently, VO₂max is estimated using HR response to submaximal exercise
- ➤ Assumes VO₂ at each exercise stage during flight same as preflight
- > The validity of this technique has not been established during or after flight

Background





- ➤ Current data suggests a sharp decline in VO₂max early in-flight and a slow recovery with participation in exercise countermeasures
- ➤ Large decline at R+5, but recovered to preflight fitness by R+30
- \triangleright Do these changes in estimated VO₂max reflect true changes?
 - > Factors such as cycling efficiency can influence the HR and VO₂ response to exercise
 - ➤ Anything affecting exercise HR response also effects the VO₂max estimate

Specific Aims

- ➤ To directly measure VO₂max during and following long duration missions
- To assess the validity of the current methods of estimating VO₂max change during and following ISS missions, and;
- ➤ To determine if the accuracy of estimating changes in VO₂max during and following ISS missions can be improved (e.g. addition of submaximal VO₂, cardiac output measures)

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Experiment Design

^{*}Represents test session not normally performed for MEDB 4.1

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Session Descriptions Preflight

SESSION: <u>Peak Cycle Exercise Test</u> on L-270 (3 weeks)

Scenario: (1 hour)

- Measure VO₂max during a cycle protocol of increasing exercise intensity
- Heart rate, blood pressure, exercise workloads, and perception of effort will also be measured
- Data obtained from this test will be used to establish the protocol for the subsequent tests
- Session is identical to that performed by all crew members under MEDB 4.1
 - Data will be shared between PI and Med Ops to prevent necessity for redundant testing

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Session Descriptions Preflight/Postflight

SESSIONS: <u>VO₂max Cycle Exercise Tests</u> on L-60, L-30, R+1, R+10 and R+30

Scenario: (1.5 hours/test preflight, 1 hour/test postflight)

- Measure VO₂max using investigation specific protocol
- First 3 exercise stages are 5 min @ work rates eliciting ~ 25, 50 and 75% of L-270 VO₂max, remaining stages increase 25 W/min to maximal levels
- First 3 stages are identical to those used in MEDB 4.1 testing
- Blood pressure, oxygen uptake, heart rate, workloads and perception of effort will be measured
- Cardiac output will be measured using a rebreathing technique during last minute of the first 3 exercise stages
- Data obtained from L-60, R+1, R+30 will fulfill MEDB 4.1 testing requirements.

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Session Descriptions Preflight/Postflight

Constraints:

- No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing
- No food 2 hrs prior to test
- No caffeine, alcohol, or nicotine 8 hrs prior to test
- No Neutral Buoyancy training 48 hours prior to test; prefer 72 hours
- ECG monitoring (up to 3 Leads) is required for tests
- No physical testing or physical training will be conducted with the crewmembers within 72 hours of returning from overseas travel
- No physical testing or physical training will be conducted with the crewmembers within 48 hours of domestic travel unless approved by the Crew Surgeon

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Session Descriptions In-Flight

SESSIONS: <u>VO₂max Cycle Exercise Tests</u> on FD 14 and every 30 FDs subsequent (same schedule as MEDB 4.1)

Scenario: (3.0 hours/test, includes equipment and subject preparation, exercise and stowage time)

- Same test protocol as performed preflight
- ECG is down-linked real time during test (Ku coverage necessary during exercise) and viewed by Surgeon for medical monitoring purposes only
- Cardiac output will be measured using a rebreathing technique during last minute of the first 3 exercise stages
- Data other than ECG will be down-linked following session

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Session Descriptions In-Flight

Constraints:

- No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing
- No food 2 hrs prior to test
- No caffeine, alcohol, or nicotine 8 hrs prior to test

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Experiment Training

Session Title	Schedule	Duration
MEC OV*	L-1 year	1 hour
CMS Ops 1*	L-1 year	1.5 hours
PPFS Hardware Overview	L-365/180 days	2 hours
VO ₂ max Integrated Training	L-160/120 days	2 hours
VO ₂ max Refresher Training	L-90/45 days	1.5 hours

MEC OV – Medical Equipment Computer Overview

CMS Ops – Countermeasure Systems Operations

PPFS – Portable Pulmonary Function System

^{*} Scheduled training is performed as outlined in MEDB 4.1

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Data Distribution

- In-flight real time data (ECG, HR, etc.) will be viewed by hardware support team to verify proper hardware configuration
- Experimental data will not be used to assess crew health
- Any data sharing will be captured in the Data Sharing Plan specific to that subject's flight

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Possible Risks or Discomforts

- > Study designated as "Reasonable Risk" by NASA CPHS
- > Many of these are already associated with MEDB 4.1
 - Muscle cramping, fatigue or soreness
 - Cycling rarely produces soreness
 - Warm-up and cool-down procedure mitigates risk
 - Subjects encouraged to stretch following the activity
 - Rash or irritation of the skin
 - Due to adhesive sensitivity (electrode site)
 - Request that electrode sites be washed/wiped following test
 - Saddle Soreness (pre/post only)
 - Padded gel seat used to minimize discomfort
 - Mouth/throat dryness
 - Drink water prior to and following test

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Possible Risks or Discomforts

Electrical shock

• All testing equipment has passed both NASA safety inspections and manufacturing electrical tests.

• Heart problems

- Vigorous exercise always carries this risk
- Sudden death ~ 1:15,000 per year in recreational joggers, ~1:50,000 per year in marathon participants (majority are medically unscreened individuals)
- Risk is mitigated by the amount of screening/testing astronauts receive
- Medical monitoring will be used (pre/post flight, flight surgeon will be present; inflight ECG monitoring/downlink will be used)

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Possible Risks or Discomforts

• <u>Dizziness Following Exercise</u>

- Most likely to occur on R+1, potential to occur during other ground tests
- May be due to blood pooling in legs, active cool down helps mitigate this
- Will monitor blood pressure and symptoms
- If necessary, subject will be moved to supine position for recovery

Perception of "air hunger"

- Cardiac output measure done with rebreathing technique
- Elevation in bag CO₂ may cause "air hunger" symptoms
- Mitigated by elevation of oxygen concentration in rebreathing gas
- Rebreathing period is short: ≤ 30 seconds; may be aborted safely if discomfort is extreme

• Accident Due to Improper Handling of Compressed Gas

• Crew and investigators will be/are trained on handling of compressed gas

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Experiment Success

Defined by:

- ➤ Direct and accurate measures of VO₂max during and following long duration missions accomplished
- ➤ Determination of the accuracy of estimating VO₂max using submaximal test results (workload vs. HR; VO₂ vs. HR)
- ➤ Determination of added benefit of cardiac output to estimates of VO₂max from submaximal test results

Experiment Benefits

- ➤ Direct measures of VO₂max will establish the "space normal" response of VO₂max to long duration space flight. This will aid in future mission planning and act as a baseline for countermeasures assessment.
- ➤ Data will allow NASA to determine if submaximal tests provide accurate information to assess VO₂max. This may have implications on the future of routine tests conducted on the ISS and interpretation of data previously collected during long duration missions.
- ➤ Will determine if the addition of the non-invasive measurement of cardiac output improves the estimate of VO₂max derived from submaximal test results.